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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,845	03/30/2004	Stephen D. Pacetti	50623.00343	6042

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EXAMINER

EDWARDS, LAURA ESTELLE

ART UNIT	PAPER NUMBER
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1734

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. **10/813,845**

Applicant(s)

PACETTI, STEPHEN D.

Examiner

Laura Edwards

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-9, 11, 12, 15-17, 19, 20, 23 and 24 is/are rejected.
- 7) ☒ Claim(s) 5, 6, 10, 13, 14, 18, 21 and 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

*Claim Rejections - 35 USC § 103*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 7-9, 11, 15-17, 19, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shim et al (US 6,372,283) in view of Sass (US 6,383,215).

Shim et al teach an apparatus for coating implantable devices comprising a CVD (chemical vapor deposition) type coating chamber (12) and a pressure controller (34) wherein the apparatus enables a coating composition to be deposited on an implantable device at a desired pressure (see col. 5. lines 7-8). Even though Shim et al are silent concerning the CVD chamber being capable of coating the implantable device with a solvent based coating composition, it was known in the art, at the time the invention was made, to coat an implantable device with a solvent based coating composition using a CVD type coating chamber as evidenced by Sass (see col.5, lines 59 to col. 6, line 25). In light of the teachings of Sass, it would have been obvious to one of ordinary skill in the art that the Shim et al CVD coating chamber would be capable of coating an implantable device with a desired coating composition even one which is solvent based. Furthermore, the recitation of the pressure controller controlling pressure in the coating chamber based on a given solvent while given consideration, has not been given substantial patentable weight because a solvent supply or a solvent based coating composition is not even required by the present claim language. Moreover, the controlling of the pressure within the chamber based on the solvent used in the coating composition is deemed a user manipulative step. As recognized by Shim et al, controlling of the pressure within the CVD chamber to control characteristics of the coating film (see col. 5, lines 2-4) is well established such that it is

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within the purview of one skilled in the art to vary and control the pressure in the coating chamber in accordance with coating composition including solvent used therein in order to control coating film characteristics on the implantable device.

With respect to claim 2, see col. 5, lines 60-62 whereby a silane composition can be sprayed on the implantable device.

With respect to claim 3, Shim et al recognize the implantable device (24) being placed on an electrode or support.

With respect to claim 7, see col. 6, lines 44+.

With respect to claim 8, see col. 4, lines 60-64.

With respect to claims 9 and 17, the apparatus of Shim et al provides a pressure controller or regulating valve capable of adjusting pressure within the coating chamber in accordance with coating film characteristics.

Claims 4, 12, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shim et al (US 6,372,283) and Sass (US 6,383,215) as applied to claims 1-3, 7-9, 11, 15-17, 19, 23, and 24 above, and further in view of Vallana et al (US 5,370,684).

The teachings of Shim et al and Sass have been mentioned above but neither Shim et al nor Sass teach a means for rotating the implantable device during coating. However, it was known in the art, at the time the invention was made, to provide in a CVD coating chamber, a rotatable support for rotating an implantable device during coating as evidenced by Vallana et al (see col. 7, lines 39-43). It would have been obvious to one of ordinary skill in the art to provide

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a rotational support as taught by Vallana et al in the CVD coating chamber of Shim et al in order to provide even coverage of coating about the entire surface of the implantable device.

*Allowable Subject Matter*

Claims 5, 6, 10, 13, 14, 18, 21, and 22 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 5 would be allowable because there is no teaching or suggestion in the prior art of an apparatus for coating implantable devices comprising the combination of a chamber in which a coating composition comprising a coating solvent can be applied to an implantable device, a pressure controller for controlling the pressure of the chamber at other than ambient pressure, such that other than ambient pressure is less than 760 torr if the coating solvent is non-volatile and wherein other than ambient pressure is greater than 760 torr if the coating solvent is volatile and further including means for moving the implantable device in a linear direction during coating.

Claim 6 would be allowable because there is no teaching or suggestion in the prior art of an apparatus for coating implantable devices comprising the combination of a chamber in which a coating composition comprising a coating solvent can be applied to an implantable device, a pressure controller for controlling the pressure of the chamber at other than ambient pressure, such that other than ambient pressure is less than 760 torr if the coating solvent is non-volatile and wherein other than ambient pressure is greater than 760 torr if the coating solvent is volatile and further including means for creating convection flow within the chamber.

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Claim 10 would be allowable because there is no teaching or suggestion in the prior art of an apparatus for coating implantable devices comprising the combination of a chamber in which a coating composition comprising a coating solvent can be applied to an implantable device, an applicator for spraying the composition on the implantable device, and a pressure controller for controlling the pressure of the chamber at other than ambient pressure, other than ambient pressure being greater than 760 torr when the coating solvent evaporation rate is to be decreased, and wherein other than ambient pressure is less than 760 torr when the coating solvent evaporation rate is to be increased.

Claim 13 would be allowable because there is no teaching or suggestion in the prior art of an apparatus for coating implantable devices comprising the combination of a chamber in which a coating composition comprising a coating solvent can be applied to an implantable device, a pressure controller for controlling the pressure of the chamber at other than ambient pressure, other than ambient pressure being greater than 760 torr when the coating solvent evaporation rate is to be decreased, and wherein other than ambient pressure is less than 760 torr when the coating solvent evaporation rate is to be increased, and further including means for moving the device in a linear direction during coating.

Claim 14 would be allowable because there is no teaching or suggestion in the prior art of an apparatus for coating implantable devices comprising the combination of a chamber in which a coating composition comprising a coating solvent can be applied to an implantable device, a pressure controller for controlling the pressure of the chamber at other than ambient pressure, other than ambient pressure being greater than 760 torr when the coating solvent evaporation rate is to be decreased, and wherein other than ambient pressure is less than 760 torr when the coating

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solvent evaporation rate is to be increased, and further including means for creating convention flow within the chamber.

Claim 18 would be allowable because there is no teaching or suggestion in the prior art of an apparatus for coating implantable devices comprising the combination of a chamber in which a coating composition comprising a coating solvent can be applied to an implantable device, an applicator for spraying the composition on the implantable device, and a pressure controller for controlling the pressure of the chamber, at a pressure, wherein pressure is other than ambient pressure and is based on the vapor pressure of the coating solvent

Claim 21 would be allowable because there is no teaching or suggestion in the prior art of an apparatus for coating implantable devices comprising the combination of a chamber in which a coating composition comprising a coating solvent can be applied to an implantable device, a pressure controller for controlling the pressure of the chamber, at a pressure, wherein pressure is other than ambient pressure and is based on the vapor pressure of the coating solvent and further including means for moving the device in a linear direction during coating.

Claim 22 would be allowable because there is no teaching or suggestion in the prior art of an apparatus for coating implantable devices comprising the combination of a chamber in which a coating composition comprising a coating solvent can be applied to an implantable device, a pressure controller for controlling the pressure of the chamber, at a pressure, wherein pressure is other than ambient pressure and is based on the vapor pressure of the coating solvent and further including means for creating convention flow within the chamber.

***Response to Arguments***

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Applicant's arguments filed 12/27/04 have been fully considered but they are not persuasive.

Applicant contends that Shim et al fails to teach or suggest a chamber capable of allowing the coating of an implantable device with a coating composition including a solvent. This argument is not deemed persuasive because Shim et al do provide a CVD type apparatus capable of allowing a desired composition to be coated on the implantable device and in support of such logic, Sass has been further provided to establish that the routineer in the art knows that an implantable device can be coated in a CVD type coating chamber using a solvent based coating system. Applicant has not positively recited a coating means in any of the independent claims such that all that is required is the capability of the Shim et al chamber to allow coating of the implantable device with a desired coating composition.

Applicant contends that Shim et al fail to teach or suggest pressure regulation based on solvent type, solvent evaporation rate, or solvent vapor pressure. However, this argument is not deemed persuasive primarily because Applicant's claimed invention does not positively require a coating composition including a coating solvent. The invention as broadly claimed merely requires that the chamber can be coated with a solvent based composition. The manipulation step of controlling pressure based on solvent type, solvent evaporation rate, or even solvent vapor pressure is deemed a user manipulative step. This step of controlling pressure has been considered but has not been given substantial patentable weight. As recognized by Shim et al, controlling of the pressure within the CVD chamber to control characteristics of the coating film (see col. 5, lines 2-4) is well established such that it is within the purview of one skilled in the art to vary and control the pressure in the coating chamber in accordance with coating composition



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including solvent used therein in order to control coating film characteristics on the implantable device.

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

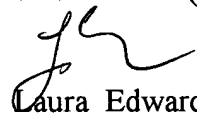
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Edwards whose telephone number is (571) 272-1227. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Fiorilla can be reached on (571) 272-1187. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Laura Edwards  
Primary Examiner  
Art Unit 1734

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March 18, 2005